

## § 184.1317

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(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32910, June 26, 1995]

## § 184.1317 Garlic and its derivatives.

(a) Garlic is the fresh or dehydrated bulb or cloves obtained from *Allium sativum*, a genus of the lily family. Its derivatives include essential oils, oleoresins, and natural extractives obtained from garlic.

(b) Garlic oil meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 132, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) Garlic and its derivatives are used as flavoring agents and adjuvants as defined in §170.3(o)(12) of this chapter.

(d) The ingredients are used in food at levels not to exceed good manufacturing practice.

(e) [Reserved]

(f) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1984]

## 21 CFR Ch. I (4-1-04 Edition)

## § 184.1318 Glucono delta-lactone.

(a) Glucono delta-lactone ( $C_6H_{10}O_6$ , CAS Reg. No. 90-80-2), also called *D*-gluconic acid delta-lactone or *D*-glucono-1,5-lactone, is the cyclic 1,5-intramolecular ester of *D*-gluconic acid. It is prepared by direct crystallization from the aqueous solution of gluconic acid. Gluconic acid may be produced by the oxidation of *D*-glucose with bromine water, by the oxidation of *D*-glucose by microorganisms that are nonpathogenic and nontoxicogenic to man or other animals, or by the oxidation of *D*-glucose with enzymes derived from these microorganisms.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 134, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a curing and pickling agent as defined in §170.3(o)(5) of this chapter, leavening agent as defined in §170.3(o)(17) of this chapter; pH control agent as defined in §170.3(o)(23) of this chapter; and sequestrant as defined in §170.3(o)(26) of this chapter.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[51 FR 33896, Sept. 24, 1986]

## § 184.1321 Corn gluten.

(a) Corn gluten (CAS Reg. No. 66071-96-3), also known as corn gluten meal, is the principal protein component of corn endosperm. It consists mainly of

zein and glutelin. Corn gluten is a by-product of the wet milling of corn for starch. The gluten fraction is washed to remove residual water soluble proteins. Corn gluten is also produced as a byproduct during the conversion of the starch in whole or various fractions of dry milled corn to corn syrups.

(b) FDA is developing food-grade specifications for corn gluten in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter and a texturizer as defined in § 170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 8998, Mar. 6, 1985]

#### § 184.1322 Wheat gluten.

(a) Wheat gluten (CAS Reg. No. 8002-80-0) is the principal protein component of wheat and consists mainly of gliadin and glutenin. Wheat gluten is obtained by hydrating wheat flour and mechanically working the sticky mass to separate the wheat gluten from the starch and other flour components. Vital gluten is dried gluten that has retained its elastic properties.

(b) FDA is developing food-grade specifications for wheat gluten in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally rec-

ognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a dough strengthener as defined in § 170.3(o)(6) of this chapter; a formulation aid as defined in § 170.3(o)(14) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter; a processing aid as defined in § 170.3(o)(24) of this chapter; a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter; a surface-finishing agent as defined in § 170.3(o)(30) of this chapter; and a texturizing agent as defined in § 170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 8998, Mar. 6, 1985]

#### § 184.1323 Glyceryl monooleate.

(a) Glyceryl monooleate is prepared by esterification of commercial oleic acid that is derived either from edible sources or from tall oil fatty acids meeting the requirements of § 172.862 of this chapter. It contains glyceryl monooleate ( $C_{21}H_{40}O_4$ , CAS Reg. No. 25496-72-4) and glyceryl esters of fatty acids present in commercial oleic acid.

(b) FDA is developing food-grade specifications for glyceryl monooleate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter and as a solvent and vehicle as defined in § 170.3(o)(27) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: